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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,163	05/21/99	SCHWAEBLE W	3523-P-002

HM22/0621

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	10

DATE MAILED: 06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic...(s)
09/163,136	Schwaeble et al.
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Apr 12, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-16* is/are pending in the applicat

Of the above, claim(s) *5-8 and 11-16* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 9, and 10* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *PCT/GB97/03275* .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *15 filed 8/23/99*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed 4/12/00 (Paper No. 9) is acknowledged and has been entered.

Claims 1-16 are pending.

2. Applicant's election of the Invention of Group I and species SEQ ID NO: 9 with traverse in Paper No. 9 is acknowledged.

Applicant's traversal is on the basis that a search of the Inventions of Groups II, III and IV in addition to Group I would not impose a serious burden on the Examiner.

Regarding applicants comments about undue burden, the M.P.E.P. § 803 (July 1998) states that: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the examinational Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-8 and 11-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions and species.

1-4, 9 and 10 are presently being examined.

The invention being examined in this application is a molecule comprising at least complement control protein modules 1-4 of complement factor H and having the sequence of SEQ ID NO: 9.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: (1) the first inventor has not initialed and dated the change to his address, and (2) the declaration does not refer to the amendment filed 5/21/99 with the request for filing a continuation of an international application.

4. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

6. The references crossed out in the Form 1449 filed 8/23/99 have not been considered.
EP 0-585-552(A1) is published in a foreign language and no translation or concise explanation of exact relevance have been provided.
A legible copy of J. Mol. Biol. 1991, 219, 717-725 has not been provided.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed molecule resulting from partial modification or an allelic mutant of a molecule comprising at least complement control protein modules 1-4 of complement factor H.

a. The instant claims encompass a multitude molecule comprising amino acid sequences that may have any number of deletions, substitutions or additions with a low degree of homology to modules 1-4 of complement factor H. There is insufficient disclosure in the specification on such a partially modified molecule or an allelic mutant.

The specification discloses (on page 3 beginning at line 13) that partial modification of the claimed molecule is a partially modified form of the molecule which retains substantially the properties of the molecule from which it is derived, although it may have additional functionality . The specification does not disclose what substantially the properties are. The specification further discloses that partially modified molecules may be homologues with at least 40% homology with the molecules from which they are derived. The specification does not disclose the definition of an allelic mutant. Thus, at the time the application was filed, the claimed polynucleotide was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

b. The instant claims encompass molecules from species other than human or rat comprising at least complement control protein modules 1-4 of complement factor H, or a molecule resulting from partial modification thereof, or an allelic mutant thereof. There is insufficient disclosure in the specification on said molecules from species other than human or rat.

The specification discloses (on page 2, last paragraph) that in human serum, two different factor H glycoproteins of 155 kDa (FHp155) and of 43 kDa (FHp43) are known. The specification further discloses rat FH 4.3 and rat FH 1.0 (on page 6 at the second full paragraph). The specification does not disclose factor H glycoproteins from species other than human or rat. Thus, at the time the application was filed, the claimed polynucleotide was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

9. Claims 1-3, 9 and 10 are rejected under 1-3, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-3, 9 and 10 are rejected under 1-3, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a molecule which consists of complement control protein modules 1-4 of human or rat complement factor H, is not enabling for a molecule comprising at least complement control protein modules 1-4 of complement factor H, nor comprising a molecule resulting from partial modification thereof, or an allelic mutant, thereof. The specification is not enabling for said molecule from a species other than rat or human consisting of at least complement control protein modules 1-4 of complement factor H, nor consisting of a molecule resulting from partial modification thereof, or an allelic mutant, thereof. The claimed molecule encompasses molecules which are not disclosed in the specification. The specification does not enable any person skilled in the art two which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims encompass a multitude molecule comprising amino acid sequences that may have any number of deletions, substitutions or additions with a low degree of homology to modules 1-4 of complement factor H. There is insufficient disclosure in the specification on such a partially modified molecule or an allelic mutant.

The specification discloses (on page 3 beginning at line 13) that partial modification of the claimed molecule is a partially modified form of the molecule which retains substantially the properties of the molecule from which it is derived, although it may have additional functionality . The specification does not disclose what "substantially the properties" are. The specification further discloses that partially modified molecules may be homologues with at least 40% homology with the molecules from which they are derived. The specification does not disclose the definition of an allelic mutant.

There is no guidance in the specification as to what alterations result in a functional molecule. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain functional activity, and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e., its activity) are not well understood and are therefore not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, Merz & LeGrand, Birkhauser Boston, pages 491-495, 1994, entire article, especially Section 6, paragraph 1), it would require undue experimentation for one of skill in the art to arrive at other amino acid sequences that would have functional activity. In other words, since it would require undue experimentation to identify amino acid sequences that have functional activity and because functional activity is defined as "substantially the properties" of the molecule from which it is derived", it would require undue experimentation to make the corresponding sequences. The enablement provided by the specification is not commensurate with the scope of the claims.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by pir62 Accession No. S03013.

Pir62 Accession No. S03013 teaches a molecule *comprising* at least complement control protein modules 1-4 of human complement factor H *having* the sequence of SEQ ID NO: 9. Note that the claimed recitation of intended use in inhibiting complement activation in instant claim 9 does not carry any patentable weight per se.

The reference teachings anticipate the claimed invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be

directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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June 13, 2000

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